

CLAIMS:

1. A drug delivery device comprising:
a resiliently flexible elongate member having a proximal end and a distal end for
5 implantation within a body;
wherein at least a portion of said elongate member is comprised of a porous biocompatible material, at least some of the pores having at least one bioactive substance disposed therein prior to implantation, said at least one bioactive substance being adapted to migrate from the pores following implantation of the member.
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2. The drug delivery device of claim 1 wherein the resiliently flexible elongate member forms part of or is used in conjunction with an implantable tissue-stimulating device having at least one electrode mounted thereon.
- 15 3. The drug delivery device of claim 2 wherein the implantable tissue stimulating device comprises a cochlear implant electrode assembly.
4. The drug delivery device of any one of claims 1 to 3 further comprising a sheath comprised at least in part of a porous material disposed over at least a portion of the
20 elongate member.
5. An implantable tissue-stimulating device comprising:
a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for
25 delivering electrical stimulation;
wherein at least a portion of said elongate member is comprised of a porous biocompatible material, at least some of the pores having at least one bioactive substance disposed therein prior to implantation, said at least one bioactive substance being adapted to migrate from the pores following implantation of the member.
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6. The implantable tissue-stimulating device of claim 5 wherein said device is a cochlear implant electrode assembly.
7. An implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation; and

5 a sheath comprised at least in part of a porous material disposed over at least a portion of the elongate member;

wherein at least some of the pores of the sheath have at least one bioactive substance disposed therein prior to implantation, said at least one bioactive substance being adapted to migrate from the pores following implantation of the member.

10 8. An implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end; and

at least one electrode mounted on the elongate member between said proximal end and said distal end for delivering electrical stimulation;

15 wherein at least one of said at least one electrode is comprised of a porous biocompatible material, at least some of the pores having at least one bioactive substance disposed therein prior to implantation, said at least one bioactive substance being adapted to migrate from the pores following implantation of the member.

20 9. The implantable tissue-stimulating device of claim 8 wherein said at least one electrode is formed from a suitable porous electrically conductive material including a porous metallic material.

25 10. The implantable tissue-stimulating device of claim 9 wherein the porous metallic material is platinum.

11. The implantable tissue-stimulating device of any one of claim 8 to 10 wherein all of the electrodes mounted to the elongate member are formed from an electrically conductive material such as a porous platinum.

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12. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein each pore of the said at least one porous portion is an individual pore within said portion, making no interconnection with another pore in said portion.

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13. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein at least some of the pores are interconnected with at least some other pores within said portion.

5 14. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein at least some of the pores are at least substantially uniform in cross-sectional shape relative to each other.

15. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-
10 stimulating device of any one of claims 5 to 11 wherein the pores vary in cross-sectional shape from one to at least some of the others.

16. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein at least some of the pores of
15 the porous portion are substantially uniform in diameter.

17. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein the pores vary in diameter from one to at least some of the others.

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18. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein the elongate member includes a plurality of porous portions and wherein each portion has substantially the same number of pores per unit area.

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19. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein the elongate member includes a plurality of porous portions and wherein at least some of the porous portions or each porous portion can have differing number of pores per unit area relative to that of at
30 least some of the other porous portions.

20. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein the bioactive substance is dispersed in a fluid including an ionic fluid.

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21. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein at least some of the pores of the at least one porous portion are changeable between a first closed configuration and a second open configuration such that upon implantation of the elongate member said
5 at least some of the pores are in their open configuration such that they release the bioactive substance held therein.

22. The drug delivery device of any one of claims 1 to 4 or the implantable tissue-stimulating device of any one of claims 5 to 11 wherein the bioactive substance is
10 selected from the group consisting of agents that promote healing, substances that prevent bleeding or at least excessive bleeding, substances that prevent the growth of tissue, including scar tissue, pharmaceutical compounds including anti-inflammatory agents, antibiotics, steroids, substances that assist in reducing the resting potential of neurons, neurotrophic factors including neurotrophins, neuropoietins, insulin-like
15 growth factors, transforming growth factors beta, fibroblast growth factors and other growth factors such as transforming growth factor alpha, platelet-derived growth factor and stem cell factor.

23. A method of delivering at least one bioactive substance to a desired site of
20 action within a cochlea using the drug delivery device of claim 1 or the implantable tissue - stimulating device of claim 5, the method comprising the steps of:
forming a cochleostomy;
inserting the elongate member through the cochleostomy;
allowing or causing the bioactive substance to migrate from the elongate
25 member into the cochlea.

24. A drug delivery device comprising:
a resiliently flexible elongate member having a proximal end and a distal end for
implantation within a body;
30 wherein at least a portion of said elongate member is comprised of a biocompatible polymeric material, having at least one bioactive substance impregnated therein, said at least one bioactive substance being adapted to diffuse from the polymeric material following implantation of the member.

35 25. A drug delivery device comprising:

a resiliently flexible elongate member having a proximal end and a distal end for implantation within the body;

wherein at least a portion of said elongate member is comprised of a biodegradable, biocompatible polymeric material having at least one bioactive substance impregnated therein, said at least one bioactive being adapted to be released upon at least partial degradation of said polymeric material.

26. The drug delivery device of claim 24 or claim 25 wherein the resiliently flexible elongate member forms part of or is used in conjunction with an implantable tissue-stimulating device having at least one electrode mounted thereon.

27. The drug delivery device of claim 26 wherein the implantable tissue-stimulating device comprises a cochlear implant electrode assembly.

28. An implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation;

wherein at least one portion of said elongate member is comprised of a biocompatible polymeric material having at least one bioactive substance impregnated therein prior to implantation, said at least one bioactive substance being adapted to diffuse from the polymeric material following implantation of the member.

29. An implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation;

wherein at least one portion of said elongate member is comprised of a biodegradable, biocompatible polymeric material having at least one bioactive substance impregnated therein, said at least one bioactive being adapted to be released upon at least partial degradation of said polymeric material.

30. The implantable tissue-stimulating device of claim 28 or claim 29 wherein the device is a cochlear implant electrode assembly.

31. The drug delivery device of any one of claims 24 to 27 or the implantable tissue-stimulating device of any one of claims 28 to 30 wherein the polymeric material is fully or partially encapsulated inside the material comprising the elongate member.
- 5 32. The drug delivery device of any one of claims 24 to 27 or the implantable tissue-stimulating device of any one of claims 28 to 30 wherein the polymeric material comprises a coating over at least a portion of the elongate member.
33. The drug delivery device of claim 24 or the implantable tissue-stimulating
10 member of claim 28 wherein the elongate member includes one or more openings to allow said at least one bioactive substance to diffuse therefrom.
34. The drug delivery device of claim 25 or the implantable tissue-stimulating device of claim 29 wherein the biodegradable polymeric material is selected from the
15 group comprising poly(acrylic acid), poly(ethylene glycol), poly(vinylpyrrolidone), poly(hydroxybutyrate), poly(lactide-co-glycolide), or polyanhydrides.
35. The drug delivery device of any one of claims 24 to 27 or the implantable tissue-stimulating device of any one of claims 28 to 30 wherein the bioactive substance is
20 selected from the group consisting of agents that promote healing, substances that prevent bleeding or at least excessive bleeding, substances that prevent the growth of tissue, including scar tissue, pharmaceutical compounds including anti-inflammatory agents, antibiotics, steroids, substances that assist in reducing the resting potential of neurons, neurotrophic factors including neurotrophins, neuropoietins, insulin-like
25 growth factors, transforming growth factors beta, fibroblast growth factors and other growth factors such as transforming growth factor alpha, platelet-derived growth factor and stem cell factor.
36. A method of delivering at least one bioactive substance to a desired site of
30 action within a cochlea using the drug delivery device of claim 24 or implantable tissue stimulating device of claim 28, the method comprising the steps of:
forming a cochleostomy;
inserting the elongate member through the cochleostomy;
allowing the bioactive substance to diffuse from the elongate member into the
35 cochlea.

37. A method of delivering at least one bioactive substance to a desired site of action within a cochlea using the drug delivery device of claim 25 or the implantable tissue stimulating device of claim 29, the method comprising the steps of:
- forming a cochleostomy;
 - 5 inserting the elongate member through the cochleostomy;
 - allowing or causing at least a portion of the biodegradable, biocompatible polymeric material to degrade, allowing release of the bioactive substance therefrom.
38. An implantable tissue-stimulating device comprising:
- 10 a lead;
 - a resiliently flexible elongate member extending from the lead and having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation; and
 - a bioactive substance delivery means adapted to deliver at least one bioactive
 - 15 substance to the implantee at a location spaced from the distal end of the member during and/or following implantation of the device;
 - wherein the substance delivery means comprises a body defining a chamber and an outlet in communication with the chamber through which bioactive substance can exit the body and further wherein the body is relatively slidably mounted to the lead of
 - 20 the device.
39. The implantable tissue-stimulating device of claim 38 wherein the device is a cochlear implant electrode assembly.
- 25 40. The implantable tissue-stimulating device of claim 38 or claim 39 wherein the outlet of the substance delivery means is positionable outside and adjacent the cochleostomy site.
41. The implantable tissue-stimulating device of any one of claims 38 to 40 wherein
- 30 the lead includes a stop means that prevents the body of the substance delivery means slidably moving relatively past the stop means and onto the elongate member.
42. The implantable tissue-stimulating device of any one of claims 38 to 41 wherein
- 35 the body of the substance delivery means comprises an annular member that is positioned around the lead of the stimulating device.

43. The implantable tissue-stimulating device of claim 42 wherein the annular member comprises a first portion and a second portion, the second portion having an outer diameter less than an outer diameter of the first portion.
- 5 44. The implantable tissue-stimulating device of any one of claims 38 to 43 wherein the outlet of the body is positioned in the distal end of the body and wherein the body includes an inlet in the proximal end of the body such that the inlet and outlet are in communication with each other.
- 10 45. The implantable tissue-stimulating device of any one of claims 38 to 44 wherein the chamber in the body acts as a reservoir for a bioactive substance and wherein the bioactive substance in the reservoir leaches from the chamber into an implantee.
- 15 46. The implantable tissue-stimulating device of any one of claims 38 to 45 wherein the outlet includes a semi-permeable membrane.
47. The implantable tissue-stimulating device of claim 44 wherein the inlet of the body is in communication with an additional reservoir for the bioactive substance, said additional reservoir positioned either external or internal the body of the implantee.
- 20 48. The implantable tissue-stimulating device of claim 47 wherein a catheter extends from the inlet to the additional reservoir and wherein a pump transfers the bioactive substance from the additional reservoir into the chamber of the body for subsequent delivery to the appropriate site of action.
- 25 49. A method of delivering at least one bioactive substance to a desired site of action adjacent a cochleostomy within a patient using a device of claim 38, the method comprising the steps of:
- 30 forming a cochleostomy;
inserting the elongate member through the cochleostomy;
closing the cochleostomy; and
slidably positioning the body of the bioactive substance delivery means adjacent the cochleostomy and allowing said at least one bioactive substance to exit therefrom.
- 35 50. The implantable tissue-stimulating device of any one of claims 38 to 49 wherein the bioactive substance is selected from the group consisting of agents that promote

healing, substances that prevent bleeding or at least excessive bleeding, substances that prevent the growth of tissue, including scar tissue, pharmaceutical compounds including anti-inflammatory agents, antibiotics, steroids, substances that assist in reducing the resting potential of neurons, neurotrophic factors including neurotrophins, 5 neuropoietins, insulin-like growth factors, transforming growth factors beta, fibroblast growth factors and other growth factors such as transforming growth factor alpha, platelet-derived growth factor and stem cell factor.